Canadian Agency for Drugs and Technologies in Health is funding initiatives such as the Canadian Platform To increase Usage of Real-world Evidence (CAPTURE) project in which physicians collaborate on gathering RWD to inform and improve standard health care practices. Finally, some US hospitals are leveraging the RWD they generate to optimize clinical and economic outcomes for their populations. Additionally, US payers are funding comparative effectiveness studies in crowded markets with costly assets and generic competition. **CONCLUSIONS:** There is a need to monitor HTA agencies' use of RWD to optimize access of the right treatments to the right patients. There is also a need to approach evidence generation in a systematic manner to differentiate assets beyond approval and initial P&R as well as to generate evidence only for those gaps that will impact health care decisions.

PHP112
EVIDENCE-BASED PRACTICE RECOMMENDATIONS: HEALTH QUALITY ONTARIO'S APPROACH
Brener SS, Nikitovic M, Chambers A, Ghazipura M, Schaink AK, Lambrinos AI, Levin L
Health Quality Ontario, Toronto, ON, Canada
OBJECTIVES: As part of the Ontario Government's health system funding reform initiative, the Evidence Development and Standards division at Health Quality Ontario (HQO) was tasked with developing episodes of care consisting of evidence-based, best practice recommendations. The HQO clinical handbooks span both medical and surgical conditions, in acute care and community based settings, and include between 25 and 100 recommendations each. The objective is to describe HQO's methodology for developing evidence-based recommended best practices for episodes of care within the rapid timelines of the government mandated funding reform. **METHODS:** Over a 1-year period, the method for deriving evidence-based recommended practices was systematically and iteratively developed by HQO clinical epidemiologists in collaboration with methodologists, clinical experts and stakeholders. **RESULTS:** The resulting approach for applying evidence to best practice recommendations included consideration of various evidence sources and consensus from expert panels which were formed for each of the clinical topics. Preference was given to existing Ontario Health Technology Assessment Committee (OHTAC) recommendations as these are developed using a decision-making framework that considers the clinical benefit offered by a health intervention, in addition to value for money; societal and ethical considerations; and economic and organizational feasibility. Where OHTAC recommendations did not exist, international guidelines were reviewed and selected based on their contextual relevance and assessment of their rigor of development using the AGREE II instrument. Uncertainty or conflict between the guidelines, or by the expert panel members, was addressed with systematic evaluations of the literature through rapid reviews and evidence-based analyses. **CONCLUSIONS:** While continually evolving to balance thoroughness and timeliness of evidence, HQO has developed a method of deriving episode of care recommended best practices set on an evidentiary base within a time-constrained government mandate.

HEALTH CARE USE & POLICY STUDIES – Patient Registries & Post-Marketing Studies

PHP113
PERCEIVED BENEFITS AND BARRIERS OF PAYER-MANUFACTURER POST-MARKETING OUTCOMES STUDY COLLABORATIONS
Olvey EL[1], Svoboda K[2], Coraggio R[2], White NP[1], Yi D[2], del Rosario C[2], Malik S[2]
[1]*NucleusX Market Access, Altanta, GA, USA,* [2]*Percipient LLC, Somerville, NJ, USA*
OBJECTIVES: To assess the currently perceived benefits and barriers of post-marketing payer-manufacturer outcomes study collaborations by US payers and pharmaceutical manufacturers. **METHODS:** Regional and national US payers and pharmaceutical manufacturers with experience in collaborative post-marketing outcomes study endeavors were invited to participate in an hour-long telephone survey. The survey consisted of questions regarding their perceptions on the benefits and barriers of potential post-marketing outcomes study collaborations, as well as attributes of potential collaborators, studies, products or diseases that would be most highly valued. Descriptive statistics were used to characterize the survey responses. **RESULTS:** A total of 12 payers and four pharmaceutical manufacturer representatives participated in the survey. Payers most often mentioned that the greatest benefit to partnering with manufacturers was the value manufacturers bring in terms of expertise and resources (58%). Benefits manufacturers identified included demonstrating consistency in outcomes data relative to randomized clinical trial data and effectiveness in real-world populations. The two most commonly cited barriers by payers regarding participation in these post-marketing outcomes research collaborations included misaligned incentives (58%) and resource intensiveness (58%). The manufacturers felt that payers are generally wary of these types of collaborations due to possible perceptions of influence, and noted that payers are usually only willing to engage and focus on high-budget impact projects and collaborations. Payers' most important consideration when selecting a pharmaceutical partner for outcomes studies was the willingness of the manufacturer to compromise and align on objectives (42%). Manufacturers agreed that alignment on objectives and expectations is critical for a successful partnership. **CONCLUSIONS:** As competition in the pharmaceutical marketplace increases and recent US health care reform moves forward, payer-manufacturer post-marketing outcomes research collaborations will be increasingly critical as a demonstration of value to all stakeholders.

PHP114
ARE PROMOTIONAL STRATEGIES OF LIFESTYLE DRUGS DIFFERENT FROM NON-LIFESTYLE DRUGS? A CONTENT ANALYSIS OF DTC PRINT MEDIA
Shanbhag P[1], Kapratwar A[1], Nayak R[2]
[1]*St. Johns University, Fresh Meadows, NY, USA,* [2]*St. John's University, Jamaica, NY, USA*
OBJECTIVES: The objective of this study was to compare the promotional strategies of life style drugs (LSD) with non-lifestyle drugs (NLSD) by content analyzing print advertisements. **METHODS:** 142 print advertisements were analyzed to see how LSD and NLSD ad messages differed with respect to rational appeals, emotional appeals and readability. Mann-Whitney U test was performed to compare the two groups of drug advertisements with respect to the type of promotional claims. Descriptive statistics were computed to summarize data pertaining to different ad features. The dataset was composed of 64 LSD advertisements and 78 NLSD advertisements. Inter- rater reliability was measured by Cohen's Kappa for two raters and was found to be adequate for all the variables used in the instrument. **RESULTS:** Significant differences were observed between LSD and NLSD ads with respect to both emotional appeals ($p= 0.000$) and rational appeals ($p=0.000$) based on Mann-Whitney U test. LSD ads focused more on emotional appeals while NLSD ads were heavy on rational content. A logistic regression analysis revealed likelihood estimates for ad claims appearing in the two groups. Readability calculated by Gunning-Fog Index for LSD's was 8.84 and for NLSD's was 11.56. Flesch-Kincaid grade level for LSD and NLSD was found to be 7.65 and 10.73, respectively, indicating increased complexity of language in NLSD ads, which was mostly reflecting of the greater use of technical scientific language. **CONCLUSIONS:** The two groups of ads clearly differed with respect to type of content, presentation, structure and complexity as well as promotional strategies adopted. Rational appeals were more predictive of NLSD ad type while emotional appeals were predominant in LSD ads.

PHP115
OPPORTUNITIES FOR THE FUTURE OF UNITED STATES MEDICAL DEVICE SURVEILLANCE: AN ANALYSIS OF THE JOINT REPLACEMENT REGISTRY (JRR) LANDSCAPE IN THE UNITED STATES
Pratt KJ, Song KM, Mitchell K
Avalere Health LLC, Washington, DC, USA
OBJECTIVES: Annually, over 1 million people in the U.S. undergo hip or knee replacements. Registries provide one mechanism to understand the benefits and risks of joint replacement in specific populations or care settings. Although countries such as Australia and Sweden have successfully established centralized JRRs, the U.S. has not. Avalere analyzed the diverse landscape of U.S. JRRs to determine the feasibility of creating one coordinated, national JRR for post-market surveillance. **METHODS:** Avalere identified JRRs in the U.S. through the International Consortium of Orthopaedic Registries participants' list, PubMed searches, abstract reviews, and web searches. Using publicly available sources, characteristics of each registry were recorded in a table. Avalere assessed this data to better understand the feasibility of harmonizing these registry efforts. **RESULTS:** In total, 25 JRRs were identified: 3 national, 4 state, and 18 local. Established between 1967 and 2011, the registries spanned 14 states with objectives including post-market surveillance, outcome improvement, research, provider feedback, and value-based purchasing. Of the 20 registries with enrollment information, 15 enrolled 1-10 hospitals, 4 enrolled 11-50 hospitals, and 1 enrolled more than 200 hospitals. One registry collected only Level I data; 2 collect Levels I-II; 9 collect Levels I-III; and 2 collect Levels I-IV; 11 registries did not have data level collection information. Registry funding sources were self-funded (n=7), publicly funded (n=1), private payer (n=1), and a combination (n=2). **CONCLUSIONS:** U.S. registries typically are established to serve the needs of their operating organization, which influences factors such as the registry's mission, recruitment efforts, and data level collected. While the number of JRRs reflects stakeholders' recognition of their value, the disparate (and sometimes competing) nature of efforts may pose challenges to the creation of a national JRR that can coordinate existing registries, ensure high quality data collection, and facilitate early surveillance to support federal regulatory needs.

HEALTH CARE USE & POLICY STUDIES – Prescribing Behavior & Treatment Guidelines

PHP116
USE OF GLASGOW ANTIMICROBIAL AUDIT TOOL (GAAT) TO ASSESS ANTIMICROBIAL USE IN THE ICUS OF AN INDIAN PUBLIC TEACHING HOSPITAL
Gudapati BNS[1], Tiwari P[2], Gombar S[3], D'cruz S[4], Sachdev A[4]
[1]*National Institute of Pharmaceutical Education and Research, Mohali, India,* [2]*National Institute of Pharmaceutical Education and Research (NIPER), S.A.S Nagar, India,* [3]*Government Medical College & Hospital, Chandigarh, India,* [4]*Government Medical College and Hospital, Chandigarh, India*
OBJECTIVES: Continuous, indiscriminate and excessive use of antimicrobial agents leads to emergence of antimicrobial-resistant organisms. Antimicrobial resistance substantially raises health care costs and influences patient outcomes (morbidity & mortality). There is a dearth of data available on appropriateness of parenteral antimicrobial therapy in the ICUs, especially in Indian settings. This study involves applying the GAAT criteria to assess the antimicrobial use. **METHODS:** This prospective observational study was carried out in the intensive care units of a public teaching hospital over a period of 12 weeks. All the relevant data was recorded in a pre-designed standardized performa and analyzed. The patients were followed for first 7 days of ICU stay and the changes made in the treatment regimen were carefully evaluated. Parenteral antimicrobial therapy was assessed for appropriateness using GAAT. Intravenous antimicrobial therapy was considered appropriate if two or more of the GAAT criteria were met. **RESULTS:** 85 ICU patients' records were screened during the study period. Out of total 85 patients, 44 patients were male while remaining 41 were females. Of these, 74 patient records were found to have complete data for studying GAAT criteria. The parenteral antimicrobial therapy was found to be appropriate in 61 patients (82%), as per GAAT criteria. **CONCLUSIONS:** Parenteral antimicrobial therapy, as per GAAT, in this study was appropriate in 82% of the patients. This is a preliminary study, future large scale studies should be carried out over a longer period of time to draw any logical conclusion.

PHP117
FACTORS PREDICTING MEDICATION OVERSUPPLY IN THAILAND: A MIXED MODEL REGRESSION ANALYSIS
Dilokthornsakul P[1], Chaiyakunapruk N[2], Nimpitakpong P[1], Jeanpeerapong N[3], Jampachaisri K[4], Lee TA[5]
[1]Center of Pharmaceutical Outcomes Research, Naresuan University, Muang, Phitsanulok, Thailand, [2]Monash University Malaysia, Selangor, Malaysia, [3]Buddhachinaraj Hospital, Muang, Thailand, [4]Naresuan University, Muang, Phitsanulok, Thailand, [5]University of Illinois at Chicago, Chicago, IL, USA
OBJECTIVES: Medication oversupply is an important problem which causes unnecessary avoidable health care costs. There are some studies determining magnitude and financial loss due to medication oversupply in western countries, they may not be applicable for Asia-pacific countries. This study aims to determine the prevalence, financial loss, and patterns of medication oversupply and factors associated with oversupply in Thailand. **METHODS:** A retrospective database analysis was conducted. Patients visiting out-patient department of 3 hospitals and receiving at least 2 prescriptions within 6 months were included. The modified medication possession ratio (MPRm) was used to determine the medication supply. Patients having MPRm>1.20 were defined as medication oversupply. The measures were prevalence of medication oversupply, the number of oversupplied medications, and financial loss due to medication oversupply. Analyses were stratified by type of hospitals. A mixed regression model was used to determine factors associated with prevalence medication oversupply. **RESULTS:** A total of 99,743 patients were included. Patients were on average 49.7±21.2 years of age, 42.8% were male. Around 13.4% of all patients had medication oversupply. Patients in regional hospital had higher prevalence of medication oversupply than patients in district hospital (13.8% VS 8.2%). Patients under civil servant medical benefit schemes (CSMBS) (13.6%) had the highest prevalence of medication oversupply. The total financial loss due to medication oversupply was $189,024 per year. The average financial loss due to medication oversupply was $1.9±19.0 per patient/year. Patients under CSMBS was highest average financial loss (2.6±23.2 $/patient/year). Age, gender, health insurance schemes, and number of medications the patients received were factors associated with medication oversupply. **CONCLUSIONS:** Medication oversupply is an important problem for the health system. Patients receiving care from regional hospital had higher likelihood of medication oversupply. Policy-makers may consider developing policies for preventing medication oversupply.

PHP118
TRENDS IN USE OF ECONOMIC EVIDENCE BY CLINICAL GUIDELINES
Aggarwal S, McGrane M
Novel Health Strategies, Bethesda, MD, USA
OBJECTIVES: The recent reforms and policy changes have increased the cost pressures on all health care stakeholders, including clinical experts. In the past, clinical guidelines were developed independent of cost or economic considerations. However, increasingly, more clinical guidelines are mentioning cost concerns and referring to economic data in new recommendations. The objective of this study was to analyze trends in the use of health economic information for developing clinical guidelines. **METHODS:** To understand trends in use of health economic information we conducted targeted search for clinical guidelines, expert recommendations, and consensus statements with specific mention of "cost" or "economic" or related terms. A systematic literature search was undertaken for the databases Pubmed, Google Scholar and Cochrane. The guidelines published between 2003-2012 were included. For guidelines which met the search criteria, data was collected for the name of the authors, indication, year of publication, country/region, and context of use of cost/economic evidence. **RESULTS:** Sixteen clinical guidelines published between 2003-2012 met the inclusion criteria for specific mention of cost/economic evidence. More than 50% of these guidelines were published between 2006-2012. For indication, 3 out of 16 guidelines were for diabetes, while the rest were for different indications. In these 16 guidelines "cost effectiveness" was mentioned 14 times, either referencing cost-effectiveness data or to mention the importance of such data for selecting treatment options. The guidelines commonly cite high cost of disease or high economic burden as one of the considerations for developing new recommendations (11 out of 16). Another term that was commonly used by these guidelines was "cost-benefit," which was mentioned 5 times in these guidelines. Notably, QALY was rarely mentioned (1 out of 16 times) in these guidelines. **CONCLUSIONS:** This analysis suggests that some clinical experts groups are increasingly showing willingness to use and incorporate health economic information for developing new recommendations

HEALTH CARE USE & POLICY STUDIES – Quality of Care

PHP119
IMPACTS OF BAR-CODE MEDICATION ADMINISTRATION (BCMA) ON PATIENTS' SAFETY IN TAIWAN
Lee M
Taipei city, Taiwan
OBJECTIVES: To analyze the current usage of BCMA enforced by the pharmacists and nurses at a medical center in Taiwan, we collected data including of the overall system satisfaction, ratio of medication errors and phone calls for tracking stat drugs. **METHODS:** The overall system's satisfaction questionnaire for nurse (n=89) and pharmacist (n=30) was designed by 8 experts using content validity index (CVI). We have collected medication error ratio for one year in order to evaluate patients' safety before and after using BCMA system. We also collected the numbers of phone calls for tracking stat drugs during Oct 2nd to Nov 15th in 2012. **RESULTS:** In pharmacists' satisfaction questionnaire, they agree BCMA system can help them recognize drugs (60%), reduce medication errors (53%) and check drug delivery (90%). But they also think BCMA has increased workload (57%). In nurses' satisfaction questionnaire, they agree BCMA system can help them increase case data's integrity (42%), patient confirmation accuracy (73%), the correct rate of administration time (47%) and the correct rate of drug administration (57%). More than half of pharmacists and nurses complain the system wasn't stable (53%, 69%) and poor barcode sensitivity (47%, 64%). The ratio of medication error was significantly reduced. (0.18%±0.042%, 0.12%±0.039%, *P* value < 0.05, n=12) From Oct 2nd to Nov 15th in 2012, we received 469 phone calls. The average of tracing call for drugs is 1.67 times every hour. **CONCLUSIONS:** Though some system problems may annoy hospital staffs, BCMA system could increase the accuracy of recognizing drugs, patients and tracing drugs. BCMA system also could significantly improve patient safety.

HEALTH CARE USE & POLICY STUDIES – Regulation of Health Care Sector

PHP120
EXTERNAL REFERENCE PRICING (ERP) IN TURKEY AND ITS EFFECTS ON COUNTRIES THAT REFER TO TURKEY
Deger C, Ozdemir AZ, Sumer F, Parali E, Yilmaz ZS, Tunalioglu A, Ustunel B, Ozel MO
Bayer Turk Kimya San. Ltd. Sti., Istanbul, Turkey
OBJECTIVES: ERP is the practice of using pharmaceutical prices in several countries to derive a price benchmark in a given country and could be used as the main criteria for pricing decisions or merely as supportive information. It is a widely used financing method worldwide and in Europe; by 2012, all EU-countries except UK and Sweden used ERP in some form. Turkey applies ERP as the main pricing criteria since 2004. This analysis aims to elaborate the Turkish ERP system with its effects on the countries referring Turkey. **METHODS:** ERP systems of Turkey and countries referring Turkey have been analyzed. **RESULTS:** Turkish reference basket is composed of Greece, Italy, France, Spain and Portugal, whose prices are relatively lower than the European-average, plus import and manufacturer countries of the product. Lowest basket price sets the price-ceiling for reimbursed products, while highest can be taken for non-reimbursed products. Reference prices are subject to an exchange rate, fixed by Ministry of Health at approximately 40% below the actual rate. Consequently, Turkish prices are almost 44% of the lowest-priced European-country. Among the countries referring Turkey, Russia and S.Arabia are the most significant markets with their size and growing potentials. Additionally, Egypt, Macedonia, Morocco, Oman and Iran refer Turkey. **CONCLUSIONS:** Although countries referring Turkey have large reference baskets, low Turkish prices could still be considered as a suppressing factor on prices in these countries. Furthermore, significant price changes especially in Russia and S.Arabia would possibly cause a second wave in some CIS and Middle East countries respectively, as they would adjust their prices within 6-12 months accordingly. Multinational companies consider this domino effect seriously and usually arrange launch sequencing to avoid inoperably-low-prices and secure the most-promising-markets. Consequently, innovative products' price levels and availability might occasionally be affected negatively in Turkey and further in countries referring Turkey.

PHP121
DESCRIPTIVE REVIEW OF THE PHARMACOVIGILANCE AND RISK ASSESSMENT COMMITTEE (PRAC) ACTIVITIES SINCE ITS ESTABLISHMENT
Acquadro C[1], Boxall N[2], Maier W[2]
[1]Mapi Research Trust, Lyon, France, [2]Mapi, London, UK
OBJECTIVES: In July 2012, the European Medicines Agency (EMA) established the Pharmacovigilance and Risk Assessment Committee (PRAC). The PRAC recommends and advises on any questions of pharmacovigilance activities related to a medicine for human use and on risk management systems. This study describes PRAC's activities to date. **METHODS:** Meeting minutes since July 2012 were retrieved from the EMA website. The PRAC received questions attributed to seven categories: EU referral procedures for safety reasons, signals assessment and prioritization, risk management plans (RMPs), assessment of periodic safety update reports (PSURs), post-authorisation safety studies (PASS), product-related pharmacovigilance inspections, and other safety issues for discussion requested by the Committee for Medicinal Products for Human Use (CHMP) or Member States (MS). **RESULTS:** There were 13 meeting minutes available (July 2012 – October 2013), containing1077 questions/requests with/without a formal decision-making phase [149 (13.9%) in 2012, 928 (86.2%) in 2013]. Three request types comprise nearly 80% (n=860): signal assessment and prioritization [n=140 (13%), 50 (4.7%) in 2012, 90 (8.4%) in 2013], RMPs [n=416 (38.7%), 48 (4.5%) in 2012, 368 (34.2%) in 2013], and PSURs [n=304 (28.2%), 20 (1.8%) in 2012, 284 (26.4%) in 2013]. PRAC outputs were recommendations or advice. In 2012, there were 46 recommendations for 35 new signal assessments requests. Recommendations regarding new signals were made either to the Marketing Authorization Holder (MAH) (n=32) (e.g., submit a cumulative review of dermatomyositis within 30 days), the EMA (n=6) (e.g., review cases of dermatomyositis and report back), the PRAC rapporteur (n=7) (e.g., assess the UK cases in the ongoing PSUR procedure) or the MS (n=1) (e.g., UK to provide a report on the nicotinic receptor mutation). **CONCLUSIONS:** After an initial "running-in period", the PRAC appears to be fulfilling its mandate. PRAC operations should be evaluated in terms of success (i.e., impact of decisions).

PHP122
THE HISTORICAL EVOLUTION OF CHINA'S DRUG REGULATORY SYSTEM
Li H, Sun H
Tianjin University, Tianjin, China
OBJECTIVES: This article makes a review on the historical evolution of China's drug regulatory system and provides some reflections and policy implications for the reform of the present system. **METHODS:** This study is based on literature review and publicly available data by searching electronic databases and official web pages of Chinese government on the internet. **RESULTS:** China's drug regulatory system has experienced complicated process of evolution. During the period of planned economy China had no independent drug regulatory system. The way to control the quality and safety of pharmaceutical products was to take full control of every